REMARKS

I. Status of Claims:

Claims 16, 17 and 19-35 are pending and stand rejected under various sections of 35 U.S.C. Claims 18 is canceled. Claim 36 has been added. Support for claim 36 is found throughout the specification and drawings. No new matter is added.

II. Rejection Under 35 U.S.C. § 101:

Claims 16-35 are rejected under 35 U.S.C. § 101 as claiming an invention deemed inoperative and lacking utility. Applicants respectfully traverse the rejection.

Submitted herewith is an article entitled, "Numerical Field Calculation of Patient Return Electrodes in Electrosurgery." The article was published in "Proceedings of Biomedizinische Technik," Vol. 47, Ergänzungsband 1, Teil 1,274-277, 2002. The article describes a neutral-ring-bearing electrode as an electrode with a "circumferential neutral ring" or "equipotential ring." The "equipotential ring" is the same as the neutral-ring-bearing electrode described and claimed in the application. Declaration Under Section 1.132 of Burrhus Lang at ¶ 4, submitted herewith. Assignor of the present application, Leonard Lang KG, manufactures neutral-ring-bearing electrodes in accordance with the teachings of the application. *Id.* at ¶ 3. A co-author of the article, J. Raiser, is an employee of a company that purchases neutral-bearing-ring electrodes from assignor Leonard Lang KG. *Id.* at ¶ 3.

The test results referenced in the article clearly establish that an electrode with a neutral ring significantly reduces heating at the skin surface and exhibits a more symmetrical heating pattern (homogeneous heat distribution) than a

conventional electrode that lacks a neutral ring. The observed symmetrical heating pattern is the direct result of the neutral ring that equalizes current distribution about the electrode. An electrode having a symmetrical current distribution pattern produces a symmetrical heating pattern when a current is applied to the electrode. The Declarant, who has a significant background in electrode technology, does not know of any conventional electrodes that produce similar results. *Id.* at ¶ 5.

The article and the testimony of Mr. Lang establish that the invention, as claimed, has utility and operates in the manner described in the application. Reconsideration and removal of the rejection of claims 16-35 under 35 U.S.C. § 101 are respectfully requested.

III. Rejections Under 35 U.S.C. § 102(b):

Claims 16-28 and 30-32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Canadian Patent No. 1,219,642. Claim 16 requires the claimed medical system have at least one current-equalizing conductor surface that lacks a connecting element, and therefore, does not connect to the claimed circuitry. These conductors perform the important function of dispersing the current evenly over an electrode's surface to improve consistency of function. Proof of this function is found in the Numerical Field Calculation article and supported by the statements of the Declarant, Mr. Lang.

As conceded by the examiner, the Canadian '642 Patent shows electrodes with elements that are *all* capable of being contacted by an electrode. None of the conductors disclosed in the Canadian '642 patent are described as current equalizing conductors that can equalize the current or improve the current density distribution over the electrode surface. In fact, this runs contrary to the clear

teachings of the reference.

The '642 patent addresses the problem of asymmetrical heat distribution produced by an electrode, but does so in a completely different manner from that described and claimed in the present application. The '642 patent electrodes are consistently described as containing multiple discreet conductive segments, each of which is attached to a resistor to control the amount of current flowing through the conductive segment. The values of the resistors are varied depending on the location of the segment, e.g., center peripheral, etc., so that the current flow through each segment is equalized. Support for this explanation is found at page 2, line 64 ("*each* section being connected to a separate resistor" (emphasis added)), and in the description of the embodiments shown in FIGS. 3 and 4 in which each conductive segment has a connector link that connects the conductive segment to a connecting tab, page 6, line 17 to page 7, line 22. *See* Lang Decl. at ¶ 7.

Based on the description of the invention in the '642 patent, removal of even one conductive segment from the energy source should nullify the heat symmetry effects of the variable resistor approach. For the '642 patent electrode to work as described, each conductive section must have energy coursing through it with a resistor of a specified resistance limiting the amount of current flow to the particular segment. It is through current control, not elimination, to each conductive segment that performs the function of symmetrical heat distribution about the electrode. Any suggestion that a conductive segment be detached from the current source runs contrary to the clear teachings of the '642 patent, renders the use of a resistor connected to that conductive segment superfluous, and amounts to an unwarranted distortion of the patent. Accordingly for these reasons, reconsideration and removal

of the rejection of claim 16, as amended, under 35 U.S.C. § 102(b) are respectfully requested.

Claims 17, 19-28 and 30-32 depend, directly or ultimately, from claim 16 and are allowable for the reasons given above. Reconsideration and removal of the rejections of claims 17, 19-28 and 30-32 under 35 U.S.C. § 102(b) are respectfully requested.

Claim 18 has been canceled without prejudice thereby rendering the rejection thereof moot.

IV. Rejections Under 35 U.S.C. § 103:

Claim 29 stands rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Canadian Patent No. 1,219,642. Applicants respectfully traverse the rejection. Claim 29 depends ultimately from base claim 16, which is allowable for the reasons given above.

Applicants again respectfully disagree with the conclusion that "it would have been obvious to modify the thicknesses of the electrodes to within such a range as an obvious design choice." There is no teaching, motivation or suggestion in the "642 patent to modify the radial widths of the electrodes to provide radially-spaced electrodes having substantially equal surface areas. Indeed, the '642 patent electrodes should not require such modifications as variable strength resistors are the means disclosed for controlling the amount of current flow to the specific conductive segments. The conclusion to modify the thicknesses of the conductive segments of the '642 patent electrodes is the result of hindsight reasoning and should not properly be made. Accordingly, the rejection of claim 29 under the rationale advanced is improper. Applicants respectfully request reconsideration and

removal of the rejection of claim 29 under 35 U.S.C. § 103(a).

V. New Claims:

Claim 36 is a claim to a medical system in substantially the form proposed by the examiner on July 18, 2006. As agreed by the examiner, nothing in the '642 Patent shows or suggests such a system. Entry and consideration of claim 36 is respectfully requested.

VI. Conclusion:

For the foregoing reasons, all the pending claims are considered to define patentably over the prior art. If, for any reason, the Examiner is inclined to further reject any of the claims, Applicants request that counsel be contacted to resolve any remaining issues. Reconsideration is requested and favorable action is solicited.

Respectfully Submitted

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TRG-299

NUMERICAL FIELD CALCULATION OF PATIENT RETURN ELECTRODES IN ELECTROSURGERY

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Abstract— *In order to examine the warming up caracteristics during application of a new electrode design for a patient return electrode of an electrosurgical system numerical field calculations were performed in this study. A multi-layer thigh model was provided for this purpose, to which the patient return electrode and the active electrode were connected. The simulation geometry as well as the dielectric tissue parameters were set according to the current frequency. The heating up at the skin surface by the flowing current was evaluated. The results were compared with experimental thermographical measurements.*

Keywords—*numerical field calculation, multi-layer thigh model, patient return electrode, thermography*

Introduction

During monopolar high-frequency (HF) electrosurgery a patient return electrode with a large contact area must be applied to the patient's skin to establish a closed electric circuit. To prevent tissue damage due to thermal heating of the return electrode induced by the current flow safety issues, such as low current densities and small transition resistances, must be strictly observed – as demanded in standards like the AAMI HF-18 [1].

The idea of a new electrode design with a circumferential neutral ring ("equipotential ring") emerged from several requirements, including a relatively small total electrode area to be able to apply the electrode to the extremities of both, adults and children, without problems. The optimal geometric shape was determined from several different return electrode designs using thermography.

By means of numerical simulations the advantageous effects of the new design have successfully been proven. Furthermore the numerical simulations enabled us to gain fundamental knowlegde for further design improvements.

Materials and Methods

In order to realize a new electrode design with an equipotential ring the standards of the American National Standard AAMI HF-18 § 4.2.3.1 [1] must be taken thoroughly into account. These standards stipulate a test procedure in which the concerned return electrode must be affixed to the skin of a test person. Then a sinusoidal current (700 mA) of an electrosurgery unit (ESU) is applied to the test person in-vivo for 60 s (cf. fig. 1).

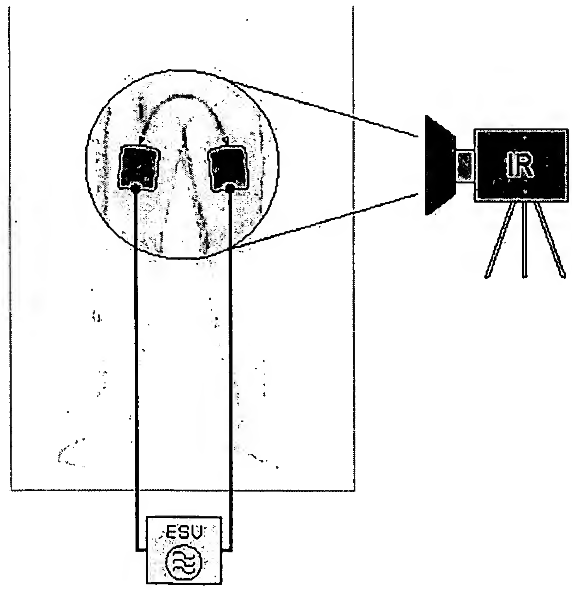

Figure 1: Diagram of the experimental setup for the safety test procedure according AAMI-standards [1]. A test person is connected to an electrosurgical unit (ESU) via two return electrodes. After the application of the test current the heating of the skin is measured using infrared (IR) thermography.

Using a suitable measurement method (in this case infrared (IR) thermography) the surface temperature of the skin is determined after peeling off the return electrode (cf. fig. 2). When using this method it is essential to ensure a minimum area of resolution of 1 cm² of the IR-camera according to [1]. In this test the maxmimum temperature rise on the thigh-surface must not exceed a limit of 6 K above the skin temperature at the beginning of the test procedure. The return electrode presented in this paper successfully passed the described test procedure.

Experimental results showed significant differences between different return electrode designs. In order to study these phenomena a multi-layer tissue model of the human thigh was designed for numerical simulations according to available anatomical data of the human body [3,4]. This model consists of a multi-layer cuboid tissue brick (cf. fig. 3) built up of different tissue types and materials. The base brick consists of skin, fat and muscle tissue where the thickness of the fat-layer was varied to simulate obese or slim test persons (cf. tab. 1). The thickness of the

remaining layers was set at an average value for humans (skin 2 mm, muscle 70 mm) [3,4]. The appropriate dielectric parameters for the different tissue types (according to the output frequency of the ESU) were taken from the tables of Gabriel [2].
A hydrogel layer was simulated between the return electrode (material: aluminum) and the skin surface in order to represent the clinical application properly. The dielectric parameters of this gel were experimentally determined prior to the numerical simulations.
The geometry of the return electrode was exactly remodelled for the numerical simulations on the basis of CAD-datasets. The modell was transformed into a 3D-mesh containing more than 800 000 cuboid voxels. The mesh resolution was varied to ensure a satisfactory approximation of the geometric specifications of the return electrode, thus facilitating numerical convergence of the solving algorithm.

The active electrode which injects the current into the thigh model was placed 200 mm away from the return electrode model (cf. fig. 3). For a worst-case assessment the return electrode was placed perpendicularly to the symmetry line, to allow an asymmetric current flow towards the return electrode, thus being most likely to produce maximum heating effects (as already proven by experiment). The peak value of the current was set at 1.41 A which corresponds to a rms-value of 1 A. The frequency was set at 350 kHz. The return electrode was connected to the active electrode via a filament, clsoing the electric circuit. To ensure numerical accuracy the total current flow through the model was evaluated using Ampère's law, calculating the line integral of the magnetic field along several closed integration paths around the model. The demanded current flow through the model and especially the hydrogel-layer could be guaranteed via this procedure.

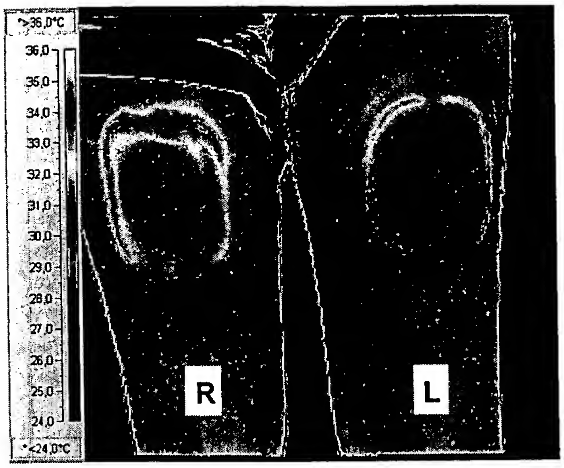

Figure 2: IR-thermography of a test person showing the local heating of the skin comparing two diffent electrode designs. The right thigh shows a conventional electrode without equipotential ring resulting in significantly higher heating of the skin than when using the return electrode with equipotential ring placed on the left thigh.

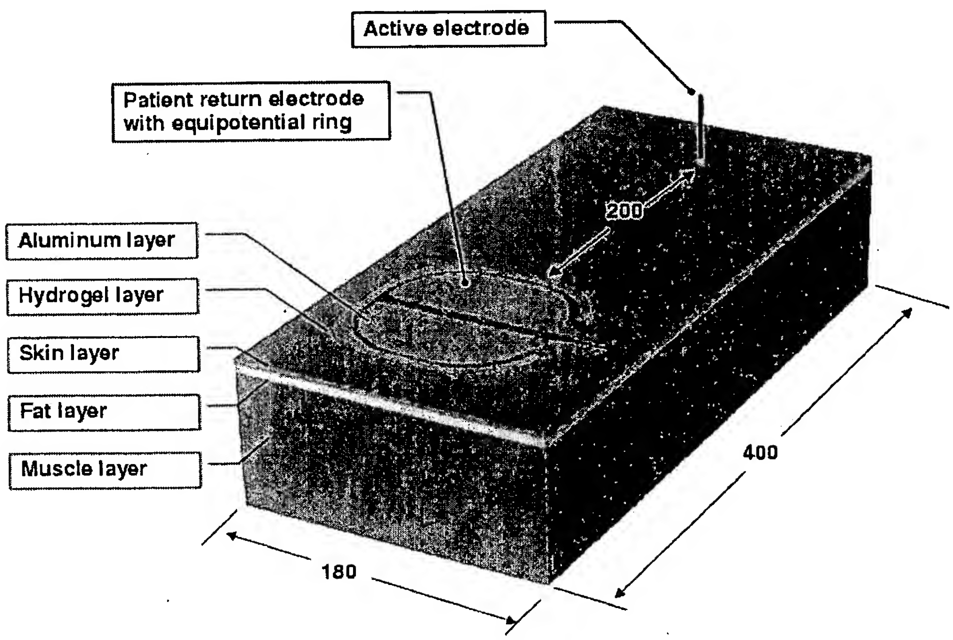

Figure 3: Setup of the numerical thigh model. The model consists of a three-layer tissue block. The tissue types are skin, fat and muscle. The figure shows the placement of the return electrode, as well as the application of the active electrode simulating the electrosurgical instrument. A hydrogel layer, acting as a contact agent, between skin and electrode was also considered to represent the clinical application as closely as possible. The active electrode and the return electrode are connected via a filament to close the electric circuit. All dimensions of the drawing are in mm.

By varying the given parameters (cf. tab. 1) eight different tissue models were set up. One parameter was the variation of the return electrode geometry. This allowed to study the effects of the equipotential ring (experimental results show a positive effect in respect to heating of the skin using return electrodes with equipotential rings). Furthermore the thickness of the fat-layer and the skin type were varied. To investigate the influence of a single parameter, calculations were performed in pairs while changing one of the significant parameters.

Simulations no. 1 and no. 2 compare the influence of the equipotential ring in a test person with dry skin, while no. 3 and no. 4 do the same for wet skin. No. 5 and no. 6 study the impact of the fat-layer in a mixed skin type (averaged values of dry and wet skin). No. 7 and no. 8 show the differences between dry and wet skin assuming a very thick fat-layer (20 mm).

The solving process for the numerical problem can be split into two different parts. First the electromagnetic problem must be solved to calculate the current flow through the tissue model. Using these values the energy absorbed in the tissue can be calculated. In a second step the calculated power loss can be used as an input parameter for solving the thermodynamic problem considering heat transfer processes, leading to a more realistic simulation.

Table 1: Parameters of the different models. In this study the thickness of the fat layer, the skin type (dry/wet) and the electrode design were varied.

No.	Skin (mm)	Fat (mm)	Muscle (mm)	Skin Type	Neutral Ring
1	2	12	70	Dry	Yes
2	2	12	70	Dry	No
3	2	12	70	Wet	Yes
4	2	12	70	Wet	No
5	2	20	70	Mix	Yes
6	2	0	70	Mix	Yes
7	2	20	70	Dry	Yes
8	2	20	70	Wet	Yes

Table 2: Specific heat capacity c_s, density ρ, permittivity ε_r and conductivity σ of the different materials used in the numercial simulations. For aluminum an ideal electric conductor was assumed.

Material	c_s (J/kg*K)	ρ (kg/m³)	ε_r ()	σ (S/m)
Aluminum	896	2702	1	∞
Hydrogel	4182	1010	1350	0.1500
Skin Dry	3663	1010	1083	0.0025
Skin Wet	3663	1010	5160	0.1565
Fat	2973	920	62	0.0437
Muscle	3639	1040	4755	0.4177

As a worst case estimation however the solution of the electromagnetic problem can be used to calculate the energy deposition in the tissue by evaluating the electrical field (Joule losses). Hence follows, taking the specific heat and the tissue density (cf. tab. 2) into account, a simple formula for a worst case assessment of the expected maximum heating of the tissue:

$$\Delta T = \frac{(\sigma + \omega\varepsilon_0\varepsilon_r)\cdot E^2}{2c_s\rho} \qquad (K/s) \qquad (1)$$

σ	conductivity	(S/m)
ω	angular frequency	(1/s)
ε_0	electrical field constant	(F/m)
ε_r	permittivity	()
E	electrical field	(V/m)
c_s	specific heat	(J/kg*K)
ρ	density	(kg/m³)

The worst case assessment implies that no heat transfer takes place at all. All deposited energy is stored locally and transformed into heat. However calculation of the heating by solving the thermodynamic problems yield more accurate results which are significantly lower than those calculated with formula (1).

Results

According to the experimental results, return electrodes with an equipotential ring are shown to produce significantly less heating at the skin surface during application of electrosurgery. A direct comparison (cf. fig. 4) yields a higher heating of the electrode without an equipotential ring on wet skin. Furthermore a characteristic asymmetrical heating pattern can be observed using electrodes without equipotential rings.

Assuming an initial skin surface temperature of 305 K the worst case assessment yields a maximum heating of the skin surface after 60 s of up to 326.3 K without the ring and up to 319.7 K with the equipotential ring. Solving the thermodynamic problem yields a maximum heating of up to 319.9 K without the ring and of up to 315.2 K with an equipotential ring. As expected these values are significantly smaller than assessed in the worst case with the equation (1).

Another interesting result was observed while comparing the effects of wet and dry skin with a 20 mm fat-layer (cf. fig. 5). The model with wet skin showed ten times more heating than the model with dry skin. This is due to higher Joule losses in the wet skin as the conductivity is more than a factor of 60 better than in the case of dry skin. This yields a higher deposited power in the wet skin since only the effective power significantly contributes to the heating effects in a low HF-frequency range. The dry skin layer is assumed to transport the energy as a capacitor, producing mostly reactive power which yields less heating of the skin surface.

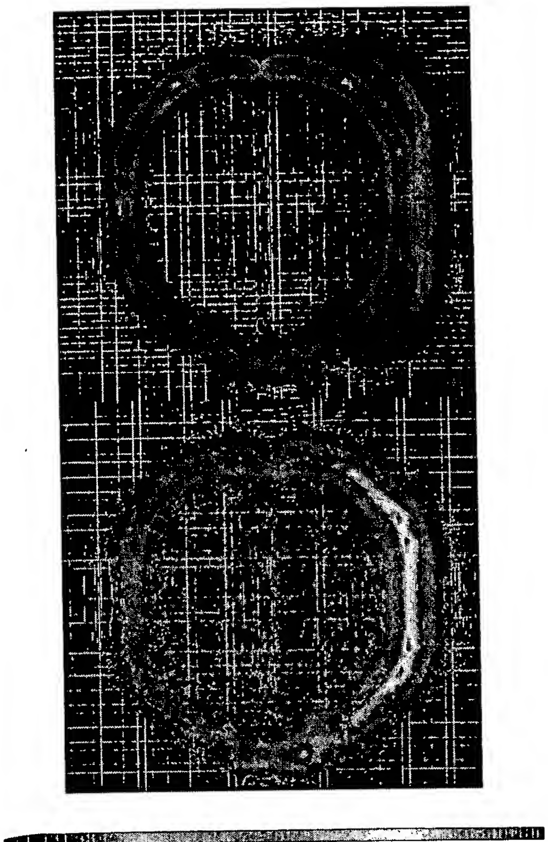

Figure 4: Heating of the skin surface (wet skin, 12 mm fat-layer) after continuous application of an electrical current (peak value 1.41 A) for 60 s, considering heat transfer mechanisms. The return electrode without an equipotential ring shows asymmetric heating and hot spots (lower image). The electrode with an equipotential ring shows less heating and a homogeneous heat distribution (upper image). For better comparison the scaling of the colorbar in both images is identical (range: 305 K to 320 K)

However the impact of the hydrogel layer must not be neglected. As the numerical calculations show, most of the effective power is directly deposited at the electrode-hydrogel transition, especially at the edge of the electrode. The electrode edges lead to a distortion of the electric field and furthermore to a concentration of the electric flux lines, hence resulting in a larger heating at the electrode edges.

Discussion

The results of the numerical calculations are in agreement with the obtained experimental results. The use of numerical techniques yielded a validation of the experimental results and a better understanding of the heating effects.

Altogether return electrodes with equipotential rings have proven to be advantageous in comparison with conventional electrodes regarding heating effects of the patients' skin, since significantly less heating occurs during electrosurgery.

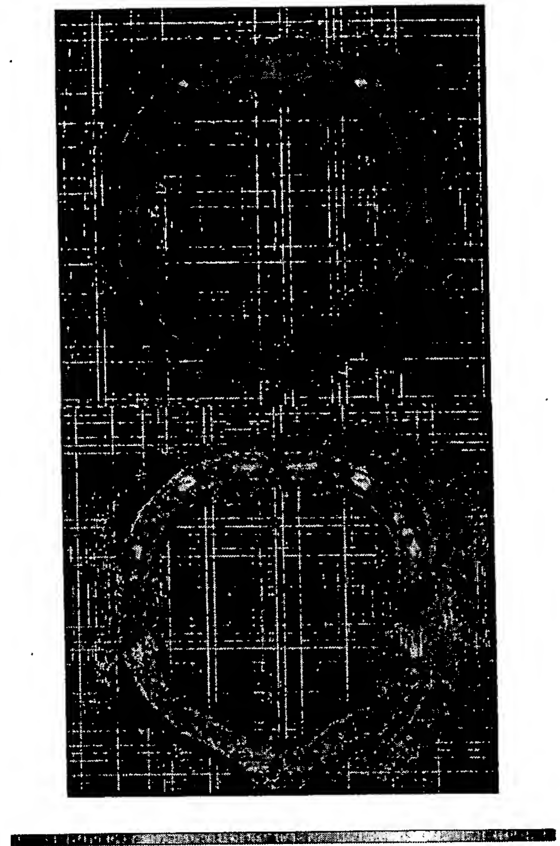

Figure 5: Heating of the skin surface (dry/wet skin, 20 mm fat-layer) after 60 s considering heat transfer mechanisms. The effects of dry and wet skin are compared. Wet skin (lower image) shows significantly higher heating than dry skin (colorbar range: 305 K to 325 K).

Return electrodes with equipotential ring also showed a widely homogeneous and symmetric heating pattern with no hot-spots. As observed, numerical simulation techniques can be used to validate the effects of new electrode designs and furthermore for numerical studies prior to expensive and time consuming experiments to ensure patient safety.

Another relevant problem is the impact of blood vessels near the skin surface and hence the formation of hot spots. This will be included in numerical studies in the future.

References

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